



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,766	09/30/2003	Thomas Albert	700706.90211	4465

7590 05/26/2006

Nicholas J. Seay
Quarles & Brady LLP
P O Box 2113
Madison, WI 53701-2113

EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT PAPER NUMBER

1634

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/674,766

Applicant(s)

ALBERT ET AL.

Examiner

Jeanine A. Goldberg

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 6-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the papers filed December 2, 2005 and April 28, 2006. Currently, claims 1-12 are pending. Claims 6-12 have been withdrawn as drawn to non-elected subject matter.
2. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow. This action is made FINAL.
3. Any objections and rejections not reiterated below are hereby withdrawn.

Maintained Rejections

Priority

1. This application claims priority to provisional application 60/415,046, filed October 1, 2002.

Drawings

2. The drawings are acceptable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1634

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-3, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al. (US Pat. 5,641,658, June 24, 1997).

Adams et al. (herein referred to as Adams) teaches a method for performing amplification of nucleic acid with two primers bound to a single solid support. Figure 2A-2D illustrates an array comprising a plurality of features (namely 121 and 123) formed of single stranded oligonucleotides. The features (namely 121 and 123) include (i.e. comprise) in the same feature more than one sequence (namely 125 and 127)(limitations of Claims 1, 2, 5). The areas (i.e. features) each contain a probe set comprising a second and third nucleic acid (col. 10, lines 15-20). Adams teaches amplification between the two nucleic acids. Therefore, the nucleic acids are attached at both the 5' and 3' ends (limitations of Claims 3). Since Adams teaches every limitation of the instant claims, Adams anticipates the claimed invention.

Response to Arguments

The response traverses the rejection. The response asserts that the claims have been amended to require a series of features all constructed on a common planar substrate. This argument has been considered but is not convincing because the supports of Adams, as seen in Figure 2 are solid planar products. It is noted that the figures of Adams illustrate beads and planar arrays.

The response asserts that Adams does not teach or suggest how a planar array could be constructed. This argument has been thoroughly reviewed but not deemed persuasive because the claims are drawn to products as clearly argued by the response. The microarray products have oligonucleotides constructed upon them. In the even that applicant intended the "constructed on" recitation to mean light directed synthesis one monomer at a time or in situ synthesis, this limitation is not in the claims and also would not change the end claimed product. The final resulting product is a microarray with oligonucleotides upon the array. How the oligonucleotides are constructed does not alter the resulting product.

Thus for the reasons above and those already of record, the rejection is maintained.

4. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Bao et al. (US Pat. 6,251,601, June 2001).

Bao teaches simultaneous measurement of gene expression and genomic abnormalities using nucleic acid microarrays. The microarray of Bao is comprised of spots with genomic DNA from 31 human putative amplified gene loci, one spot of total human genomic DNA, three control spots of pooled genomic DNA, each spot a pool of equal amounts of genomic DNA for ten of these oncogene loci, and one spot of lambda phage DNA (col. 26, lines 40-46). The microarray thus comprises several features (i.e. nearly 35 features). The features include more than one sequence (i.e. genomic DNA or 10 oncogene loci). Therefore, Bao teaches every limitation of the instant claims.

Response to Arguments

The response traverses the rejection. The response asserts that Bao does not teach or suggest that the oligonucleotides are constructed and arranged on a planar substrate. This argument has been thoroughly reviewed but not deemed persuasive because the claims are drawn to products as clearly argued by the response. The microarray products have oligonucleotides constructed upon them by spotting. Taking a probe and immobilizing it constitutes constructing it on the support. In the even that applicant intended the "constructed on" recitation to mean light directed synthesis one monomer at a time or in situ synthesis, this limitation is not in the claims and also would not change the end claimed product. The final resulting product is a microarray with oligonucleotides upon the array. How the oligonucleotides are constructed does not alter the resulting product.

Thus for the reasons above and those already of record, the rejection is maintained.

5. Claims 1-2, 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Gentalen et al. (US Pat. 6,306,643, October 23, 2001).

Gentalen teaches a method of using an array of pooled probes in genetic analysis. The invention provides arrays of polynucleotide probes having at least one pooled position. Gentalen illustrates an array comprising two probes with two polymorphisms and each of the 4 possible alleles for the two polymorphisms. The "paired array" therefore has 16 features with two probes. The resulting array contained

16 sites, each with a different combination of N1 and N2 in the two probes (col. 5, lines 35-40)(limitations of Claims 1-2). Gentalen teaches that the nonoverlapping sequences include first and second polymorphic sites and the first and second probes are respectively complementary to polymorphic forms of the first and second polymorphic sites (col. 2, lines 50-60). Gentalen teaches that multiple cells in the array contain different pooled mixtures of probes which are useful for analyzing targets that can have multiple combinations of segments (col. 9, lines 35-45). Therefore, Gentalen teaches an array comprising features with pooled nucleic acids at particular positions.

Response to Arguments

The response traverses the rejection. The response asserts that Gentalen teaches an array with two probes with polymorphisms and arranged in a specific designed position where by each of the potential polymorphisms is paired in a specific relationship. The response asserts that Gentalen does not envision an array which is formed in which each of features has a pair of oligonucleotides which are different in nucleotide sequence. This argument has been thoroughly reviewed but not deemed persuasive because as noted by the response "Gentalen teaches an array with two probes with polymorphisms and arranged in a specific designed position where by each of the potential polymorphisms is paired in a specific relationship". Thus, Gentalen does teach two probes which are different in nucleotide sequence.

Thus for the reasons above and those already of record, the rejection is maintained.

6. Claims 1-2, 4-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Shah (US Pat. 6,808,886, October 26, 2004).

Shah teaches methods for array-based comparative binding assays. Shah teaches that each array can comprise a calibration spot, wherein the calibration spot comprises a biological molecule from each spot on an array (col. 6, lines 55-65). The at least one calibration spot comprises at least one copy of a sequence from each test spot on the array. Shah teaches an array having 100 spots that represent the sequences of substantially a complete chromosome or a known subset of a chromosome or an entire genome. The 101st spot, a calibration spot has at least one sample of nucleic acid from each of the 100 test spots (col. 24, lines 50-65). Since Shah teaches every limitation of the instant claims, Shah anticipates the claimed invention.

Response to Arguments

The response traverses the rejection. The response asserts that Shah does not teach or suggest that the oligonucleotides are constructed and arranged on a planar substrate. This argument has been thoroughly reviewed but not deemed persuasive because the claims are drawn to products as clearly argued by the response. The microarray products have oligonucleotides constructed upon them by spotting. Taking a probe and immobilizing it constitutes constructing it on the support. In the event that applicant intended the "constructed on" recitation to mean light directed synthesis one monomer at a time or in situ synthesis, this limitation is not in the claims and also would not change the end claimed product. The final resulting product is a microarray with

oligonucleotides upon the array. How the oligonucleotides are constructed does not alter the resulting product.

Thus for the reasons above and those already of record, the rejection is maintained.

New Grounds of Rejection Necessitated by Amendment

New Matter

4. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the amended claims, reference to “constructed on and arranged on a common planar substrate” are included. The amendment does not teach or identify where the newly added recitation is supported by the instant specification. The specification appears to discuss a slide, which is one planar substrate, but does not generally describe any planar substrate. The concept of “constructed on and arranged on a common planar substrate” does not appear to be part of the originally filed invention. Therefore, “constructed on and arranged on a common planar substrate” constitutes new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Conclusion

7. No claims allowable over the art.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1634

The Central Fax Number for official correspondence is (571) 273-8300.


Jeanine Goldberg
Primary Examiner
May 24, 2006